

OCT 13 2005

Summary of Safety and Effectiveness

Submitter: Zimmer Orthopaedic Surgical Products
200 West Ohio Avenue
P.O. Box 10
Dover, Ohio 44622

Contact Person: Cindy J. Dickey
Regulatory Compliance Manager
Telephone: (330) 364-9493
Fax: (330) 364-9490

Date: August 8, 2005

Trade Name: ZIMMER AMBULATORY PUMP KIT, PAIN
MANAGEMENT SYSTEM with PCM

ZIMMER AMBULATORY PUMP KIT, PAIN
MANAGEMENT SYSTEM, 3/5/8 ml/h

Peelable Introducer Needle Kit

Fixed Hub Catheter Kit

Common Name: Pump, Infusion, Elastomeric

**Classification Name
and Reference:** Pump, Infusion, Elastomeric
21 CFR § 880.5725

Predicate Devices: Zimmer Ambulatory Pump Kit Pain Management
System manufactured by Zimmer Orthopaedic
Surgical Products, K050433, cleared April 13,
2005.

Device Description: The Zimmer Ambulatory Pump Pain Management
System is a convenience kit that is comprised of
legally marketed devices. The devices are
purchased non-sterile and subsequently packaged in
tray kits by Zimmer. Once packaged, the kit will be
sent to a contract sterilizer for irradiation

sterilization. The proposed convenience kit does not change the intended use of the legally marketed devices which comprise the kit.

The *Zimmer* Ambulatory Pump Pain Management System (kit) does not raise any new safety and effectiveness concerns when compared to the similar legally marketed devices. The *Zimmer* Ambulatory Pump Pain Management System should therefore be considered substantially equivalent to the existing predicate devices.

Indications for Use:

The *Zimmer* Pain Management System and Zimmer Pain Management System with Patient Control Module (PCM) are indicated for the slow, continuous, subcutaneous or epidural administration of pain medications. It may also include the slow, continuous infusion of pain medications directly into an intraoperative, subcutaneous, or epidural site for postoperative pain management or the continuous infusion of a local anesthetic near a nerve for regional anesthesia. The PCM allows for intermittent bolus doses of medication on patient demand. The system is convenient for use by ambulatory patients. It is the responsibility of the user to assure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.

Comparison to Predicate Device:

The *Zimmer* Ambulatory Pump Pain Management Kit (with and without PCM) and alternative introducer needle and catheter kits are substantially equivalent to the legally marketed pain management kits, specifically the *Zimmer* Ambulatory Pump Pain Management System in that the kits are similar in design, materials, and indications for use.

Performance Data (Nonclinical

Non-Clinical Performance and Conclusions:

and/or Clinical):

The devices in this kit have been tested to determine the impact of sterilization as per the guidance document, "Sterilized convenience kits for clinical and surgical use; final guidance for industry," January 7, 2002 was utilized as guidance for this submission.

The previously cleared devices have been tested and does meet the applicable sections of the ANSI/AAMI/ ISO 10993-1:1997, "Biological evaluation of Medical Devices."

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this kit.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 13 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cindy J. Dickey
Regulatory Compliance Manager
Zimmer Orthopaedic Surgical Products
200 West Ohio Avenue
P.O. Box 10
Dover, Ohio 44622-0010

Re: K052171

Trade/Device Name: Zimmer Ambulatory Pump Pain Management System and
the Zimmer Ambulatory Pump Pain Management System with
PCM

Regulation Number: 21 CFR 880.5725

Regulation Name: Infusion Pump

Regulatory Class: II

Product Code: FRN

Dated: September 19, 2005

Received: September 26, 2005

Dear Ms. Dickey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer Ambulatory Pump Pain Management System and the Zimmer Ambulatory Pump Pain Management System with PCM

Indications for Use:

The *Zimmer Pain Management System and Zimmer Pain Management System with Patient Control Module (PCM)* are indicated for the slow, continuous, subcutaneous or epidural administration of pain medications. It may also include the slow, continuous infusion of pain medications directly into an intraoperative, subcutaneous, or epidural site for postoperative pain management or the continuous infusion of a local anesthetic near a nerve for regional anesthesia. The PCM allows for intermittent bolus doses of medication on patient demand. The system is convenient for use by ambulatory patients. It is the responsibility of the user to assure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Chris D. [Signature] Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Anesthesiology General Hospital,
Infection Control, Dental Devices

510(k) Number. K052171